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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,242	06/24/2003	Ye Fang	SP02-143	1181
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EXAMINER				
YANG, NELSON C				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/602,242

Applicant(s)

FANG ET AL.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-8, 10-18, 27 and 42-61 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6-8 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 10-18 and 42-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 4, 42, 49, and 57 is acknowledged and has been entered.
2. Applicant's cancellation of claims 2, 9, is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 4-5, 10-18, 42-61 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1, 42, and 57 recite the limitation of "providing a humidity equilibrated array". However, the term "humidity" is typically used as a reference to the amount of water vapor in the air. Since applicant has not indicated what the humidity the array is being equilibrated to, it is unclear how one of ordinary skill in the art would equilibrate the array, as it is unclear if applicant is attempting to equilibrate the water content of the array to a specific amount, and if so, what amount, thus rendering the claim indefinite. Since applicant has cited p. 13, lines 8-11 as providing support for this limitation, the limitation has been interpreted as being exposed to a humid chamber.
6. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 42-48, 53, 54, 57-61 are rejected under 35 U.S.C. 102(c) as being anticipated by Fang et al. [US 2002/0094544].

With respect to claims 42, 57, Fang et al. teach an array comprising a plurality of biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (para. 0009), wherein the surface is coated with an amine presenting molecule (para. 0016-0017). The biological membrane microspots comprise a membrane bound protein such as G-protein coupled receptors or G-proteins (para. 0009), which would bind to toxins such as C5a anaphylatoxin and pertussis toxins. Fang et al. further teach detection of a binding event using the probe array.

9. With respect to claims 43-44, Fang et al. further teach that the analyte may be labeled and detected by fluorescence (para. 0103).

10. With respect to claim 45, Fang et al. teach washing to remove unbound targets (para. 0104).

11. With respect to claim 46, Fang et al. teach that the array of microspots is incubated with labeled cognate target and an unlabeled target compound, and the binding event between the unlabeled target compound and the probe is determined by measuring a decrease in the signal of

the label due to competition between the cognate labeled target and the unlabeled target compound for the probe (para. 0033).

12. With respect to claim 47, Fang et al. teach detecting a physical change in physical properties at the interface due to a binding event between the target and the probe (para. 0033), wherein the target is unlabeled (para. 0033).

13. With respect to claim 48, Fang et al. teach measuring a change in refractive index (para. 0033).

14. With respect to claim 53, Fang et al. teach coating with γ -aminopropylsilane (para. 0015).

15. With respect to claim 54, the amines used by Fang et al. may be polyethylencimine (para. 0068).

16. With respect to claims 58-60, Fang et al. teach coating with γ -aminopropylsilane (para. 0015).

17. With respect to claim 61, Fang et al. teach alkane thiolates derivatized with silanes (para. 0024).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 1, 4, 10-16, 18, 52, 57-58, 60, 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Fang et al. [US 2002/0094544] in view of Umek et al. [US 2003/0124572].

With respect to claim 1, Fang et al. teach an array comprising a plurality of biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (para. 0009), wherein the surface is coated with an amine presenting molecule such as thioalkyl amine (para. 0016-0017). The biological membrane microspots comprise a membrane bound protein such as G-protein coupled receptors or G-proteins (para. 0009), which would bind to toxins such as C5a anaphylatoxin and pertussis toxins. Fang et al. further teach detection of a binding event using the probe array. Fang et al., however, do not specify monitoring for binding activity of at least one of the biological lipid membranes with toxin in a sample

Umek et al., however, teach screening toxins against a plurality of cell targets (para. 0060) and measuring the effects of toxins (para. 0089) using immobilized lipid layers (para. 0048, 0094), wherein the lipids may further comprise membrane components such as G-protein coupled receptors (para. 0056), thus forming doped lipids with moieties (G-protein coupled receptors) capable of binding to toxins (para. 0089).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the arrays of Fang et al. to screen and measure the effects of toxins against a plurality of cell targets, in order to be able to predict the interactive effects of toxins on cells in the human body.

20. With respect to claims 10, 11, 14, Fang et al. further teach that the analyte may be labeled and detected (para. 0103), while Umek et al. teach labeled binding reagents specific for the

analytes (para. 0080, 0093)), and that the analytes may comprise toxins (para. 0060), which would result in labeled toxins that are then measured (para. 0093).

21. With respect to claim 12, Fang et al. teach detecting a physical change in physical properties at the interface due to a binding event between the target and the probe (para. 0033).
22. With respect to claim 13, Fang et al. teach unlabeled target (para. 0033).
23. With respect to claim 15, Fang et al. teach synthetic or natural analytes, while Umek et al. analytes which may be toxins (para. 0060), as discussed above.
24. With respect to claims 16, 18, Fang et al. teach glass slides (para. 0012).
25. With respect to claim 17, Fang et al. teach porous substrates (para. 0067).

With respect to claim 49, Fang et al. teach an array comprising a plurality of biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (para. 0009), wherein the surface is coated with an amine presenting molecule such as thioalkyl amine (para. 0016-0017). The biological membrane microspots comprise a membrane bound protein such as G-protein coupled receptors or G-proteins (para. 0009), which would bind to toxins such as C5a anaphylatoxin and pertussis toxins. Fang et al. further teach detection of a binding event using the probe array. Fang et al., however, do not specify monitoring for binding activity of at least one of the biological lipid membranes with toxin in a sample.

Umek et al., however, teach screening toxins against a plurality of cell targets (para. 0060) and measuring the effects of toxins (para. 0089) using immobilized lipid layers (para. 0048, 0094), wherein the lipids may further comprise membrane components such as G-protein

coupled receptors (para. 0056), thus forming doped lipids with moieties (G-protein coupled receptors) capable of binding to toxins (para. 0089).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the arrays of Fang et al. to screen and measure the effects of toxins against a plurality of cell targets, in order to be able to obtain information on the interaction of toxins on cells in the human body.

1. With respect to claims 51, 55, as discussed above, the amines used by Fang et al. may be γ -aminopropylsilane (para. 0015).
2. With respect to claims 52, 56, as discussed above, the amines used by Fang et al. may be polyethylencimine (para. 0068).
3. With respect to claims 60 and 61, as discussed above, the amines used by Umek et al. may be silanes containing such as alkoxysilanes (para. 0073).
4. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fang et al. [US 2002/0094544] in view of Umek et al. [US 2003/0124572], as applied to claim 1 above, and further in view of Lofas [US 5,922,594]

With respect to claim 5, Fang et al. teach the invention as discussed above, but fail to teach toxin binding moieties such as carbohydrates, or more specifically, gangliosides.

Lofas, however, teaches liposomes containing ganglioside G_{M1} for detecting cholera toxins in a sample (column 5, 6, example 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used gangliosides such as G_{M1} , as suggested by Lofas et al., in order to be able to detect the presence of cholera toxin in a sample.

Response to Arguments

26. Applicant's arguments with respect to claims 1, 4-5, 10-18, 42-61 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

27. No claims are allowed.

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Patent Examiner, Art Unit 1641